SECTION 2. 510(K) SUMMARY

510(k) Summary (as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)3A of the Safe Medical Devices Act of 1990, TyRx Pharma, Inc. is providing a summary of the safety and effectiveness information available for TyRx Surgical Mesh, as well as the substantial equivalence decision making process used for TyRx Surgical Mesh.

Sponsor/Applicant Name and Address:
TyRx Pharma, Inc.
1 Deer Park Drive, Suite G
Monmouth Junction, NJ 08852

Sponsor Contact Information:
Mason Diamond, DDS
Vice President, Clinical and Regulatory Affairs
Phone: 732-246-8676
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Date of Preparaton of 510(k) Summary:
October 6, 2005

New Device Trade/Proprietary Name:
TyRx Surgical Mesh

Device Common/Classification Name:
Polymeric Surgical Mesh

Predicate Devices Name and 510(k) Numbers:
VYPRO Mesh VICRYL-PROLENE partially absorbable synthetic surgical mesh (K002672)
PROLENE polypropylene mesh nonabsorbable synthetic mesh (K962530)
GORE POLYPROPYLENE HERNIA Mesh (K043081)

Device Description:
TyRx Surgical Mesh is dual component (resorbable and non-resorbable), sterile prosthesis designed for the reconstruction of soft tissue deficiencies. TyRx Surgical Mesh is constructed of a non-resorbable mesh comprised of knitted filaments of polypropylene and a bioresorbable polyarylate coating on the mesh. The resorbable coating represents approximately 10% of the total weight of the device. The purpose of the resorbable coating is to provide additional stiffness to the mesh in order to facilitate interoperative handling during placement. Once placed, the polymer resorbs in approximately 90 days leaving a lighter permanent mesh incorporated into the tissue. In

addition, animal testing demonstrated that TyRx Surgical Mesh would achieve satisfactory tissue ingrowth compared to commercial surgical mesh.

Intended Use:
TyRx Surgical Mesh is intended for the repair of hernias and other abdominal fascial deficiencies requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. Examples of applications where TyRx Surgical Mesh may be used include, but are not limited to: inguinal, femoral, umbilical, abdominal, incisional and intramuscular hernias and muscle flap reinforcement.

Performance Data:
Non-clinical laboratory testing was performed in accordance with the FDA guidance document "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh" demonstrating that the device is comparable to standard surgical mesh devices that are indicated for hernia repair and other abdominal fascial or muscular deficiencies requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. The TyRx Surgical Mesh and the polyarylate polymer have been demonstrated to be biocompatible. In addition, animal testing demonstrated that TyRx Surgical Mesh will achieve satisfactory tissue ingrowth compared to control as evidenced by histopathology.

Conclusions:
Based on the 510(k) summaries (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2005

Mr. Mason W. Diamond, D.D.S.
Vice President, Clinical & Regulatory Affairs
TyRx Pharma, Inc.
1 Deer Park Drive, Suite G
Monmouth Junction, New Jersey 08852

Re: K052864
Trade/Device Name: TyRx Surgical Mesh, Model SMPC-0501
Regulatory Number: 21 CFR 878.3300
Regulatory Name: Implantable clip
Regulatory Class: II
Product Code: FTL
Dated: December 2, 2005
Received: December 6, 2005

Dear Dr. Diamond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

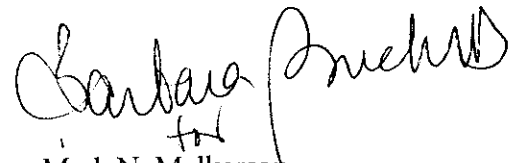
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1. INDICATION FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K052864

Device Name: TyRx Surgical Mesh

Indications for Use:

Is intended for the repair of hernias and other abdominal fascial deficiencies requiring the addition of a reinforcing or bridging material to obtain the desired surgical result. . Examples of applications where TyRx Surgical Mesh may be used include, but are not limited to: inguinal, femoral, umbilical, abdominal, incisional and intramuscular hernias and muscle flap reinforcement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jenbare Brchup for NXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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